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ment and treatment titration for maximal clinical benefit. In this paper, we present the rationale for and implementation challenges of the Diabetes Telephone Study (DTS), a randomized trial designed to improve quality of life among newly treated DPN patients. **METHODS:** This pragmatic cluster randomized controlled trial tests whether collecting and feeding back real-time patient-reported data about experiences with newly prescribed DPN medicines can improve treatment outcomes. Randomization occurred at the physician level and patients are prospectively identified as they receive a new DPN-related prescription (October 2014 - November 2015). Patients in the intervention group report on medication taking behavior, symptoms, side effects, self-titration and satisfaction with treatment during three interactive automated calls during the six months following a new prescription. This information is entered into the electronic medical record and, among patients experiencing problems (e.g., side effects), flagged for immediate physician follow-up. We compare outcomes (quality of life, medication changes, patient-physician communication) for the intervention group to those in a control group who receive similarly timed non-interactive automated calls consisting of diabetes educational messages. **RESULTS:** We designed this study to minimize common threats to internal validity, including ascertainment bias and contamination. However, stakeholder engagement has been critical for tailoring the intervention to address pragmatic concerns such as provider time constraints and patient characteristics. **CONCLUSIONS:** Innovative strategies are needed to guide improvements in health care delivery for patients with symptomatic DPN. If successful, this intervention provides a critical information feedback loop that would optimize DPN medication titration through widely available interactive voice response technology.

PRM235
LETS TALK! IS CHATTER ON SOCIAL MEDIA AMONGST PARTICIPANTS COMPROMISING CLINICAL TRIALS?

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OBJECTIVES: The number of patients posting on health-related social media (SM) sites about their experiences is increasing exponentially. There have been well-publicised cases where trial participants blog and discuss all kinds of details about the clinical trials (CTs) in which they are participating. There has been expression of concern that this could compromise the integrity of CTs. The primary objective of this study was to explore how frequently CTs were discussed in selected patient SM sites and to characterise the types of discussions taking place and how they might impact on clinical trials. **METHODS:** Diabetes and breast cancer were selected as the target conditions as these have a large number of clinical trials and patient-related SM discussions with high participation levels. Over one million postings identified from the largest United States and United Kingdom-based SM sites were evaluated for content relating to discussion of CTs **RESULTS:** Over 1 million posts were reviewed with 0.9% of posts mentioning clinical trials. The average number of views of postings mentioning CTs were 1,025 which was just lower than the average of 1,147 for all posts. Discussions of active CTs by participants were rare. There were no discussions in the sample that risked un-blinding of CTs. There were equally discussion encouraging and discouraging clinical trials. Overall there were 37 threads which debated whether to join clinincal trials or not. Two patient SM sites had recently added CT specific forums. **CONCLUSIONS:** Use of SM by clinical trial participants is growing, and there is a potential for both harm and benefit in these discussions and in their visibility through a browser. Trial participants should undergo some basic training on the risks of SM discussion and those running CTs may need to consider the potential impact of social media on the trial and consider periodic monitoring of SM content.

PRM236
TRANSLATION INTO RUSSIAN AND VALIDATION OF THE COCHRANE QUESTIONNARIE TO ASSESS RISKS OF SYSTEMATIC BIASES IN RANDOMIZED CONTROLLED TRIALS

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OBJECTIVES: The questionnaire of the Cochrane Collaboration developed to assess risks of six key systematic biases in randomized controlled trials (RCT) is needed for wide use in Russia, so it was translated into Russian and validated. **METHODS:** Two experts (F.V.K. and K.G.R.) with 4-year experience of evidence assessment used the Russian version of the questionnaire to consider biases in 20 RCT published in 2002-2012. The inter-rater agreement was estimated using Kappa (K) coefficient, it was calculated for six key domains and also for overall summarizing risk of bias (low, high, unclear) within a study (across domains). **RESULTS:** Two experts demonstrated good, very good and excellent agreement on each key domain and also good overall summarizing agreement (K=0.767, 95% CI 0.527; 1.000). We propose to consider the conflict of interests not as additional but as obligatory (the 7th) key domain (the agreement in this domain is very good, K=0.840, 95% CI 0.641; 1.000). As it appeared to influence greatly the overall estimation summarizing risk we also propose to modify slightly the Cochrane rule of summary assessment of the risk of bias (across domains). The modified rule allows unclear risk of bias in one key domain to have low overall summarizing risk. The final version of the document also provides good agreement (K=0.785, 95% CI 0.503; 1.000). **CONCLUSIONS:** The Russian version of the Cochrane questionnaire is ready to use also as a web-based tool.

PRM237
USING INCENTIVES TO IMPROVE HEALTH-RELATED BEHAVIOURS: A REVIEW OF INCENTIVE-BASED TRIALS

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OBJECTIVES: Incentive-based interventions aim to improve health outcomes by rewarding individuals for specific health-related behaviours such as exercise, medication adherence or smoking cessation. Since the types and targets of incentives are varied, this study aimed to review the characteristics of ongoing studies of incentive-based interventions. **METHODS:** A targeted search was conducted in ClinicalTrials.gov using the search terms "incentive", "reward", "contingency", "contingency management", "prize", "reinforcement", "token", "voucher", "conditional cash transfer", "CCT, "pay for performance" or "P4P". Studies were selected for inclusion if they investigated the use of ≥1 incentive in modifying health-related behaviour, had the status "active, not recruiting," and the effect of incentives was distinguishable between study arms. **RESULTS:** Of the 204 search results, 42 met the inclusion criteria. The majority of these studies (n=29) took place in North America, and almost half (n=20) investigated the use of a financial reward or voucher as the incentive. The rationale for the use of an incentive was most commonly the promotion of healthy lifestyle choices relating to diet and physical activity (n=17), whilst other studies targeted behaviours such as medication/treatment adherence (n=9) or breaking addiction (n=8). The use of incentives in the management of chronic conditions or diseases such as hypertension, diabetes or HIV was investigated in 11 of the included studies. **CONCLUSIONS:** These initial results show that ongoing studies of incentives predominantly investigate the promotion of healthy lifestyle choices, with financial rewards or vouchers being the most common form of incentive. This emphasis on promoting healthy lifestyle choices may reflect the difficulties that individuals otherwise have in achieving these complex behavioural changes, and perhaps the importance of these changes to healthcare systems worldwide. Studies which assess the use of inventive-based interventions for modifying health-related behaviours, or compare the effectiveness of different incentives in improving outcomes, warrant further investigation.

PRM238
A MIXED METHODS STUDY OF RESEARCHERS' EXPERIENCES OF DEVELOPING CORE OUTCOME SETS

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OBJECTIVES: A core outcome set (COS) is a standardised set of outcomes which should be measured and reported, as a minimum, in all effectiveness trials for a specific health area. A systematic review of COS identified 198 COS [1]. A range of methods were used, and furthermore, 164/178 studies that described the methods used did not provide an explanation regarding their choice of methodology. There is little guidance about how to conduct or report COS studies and it is currently uncertain which of these methods are the most suitable, feasible and efficient. It is important to investigate COS developers' choice of approach as this is a new area of research, and in order to formulate guidance in this area we need to try and understand the current situation, including the influences of methodological choices being made. **METHODS:** We have used a mixed methods approach, using qualitative methods (semi-structured interviews) and a web-based survey. **RESULTS:** Interviews are currently underway. The survey was sent out to 169 COS developers, with 81/169 responses. Methodological decisions were based most commonly on previous work, expert advice or own experience. Challenges of this work included resources (time, funding and technology), achieving consensus, a lack of data and challenges with involving patients in the process. **CONCLUSIONS:** In order to develop methodological guidance for COS development we need to try to understand what factors have informed the ways in which researchers have developed COS. This is the first insight into COS developers' choice of methodology and their experiences of the process. These results will provide a more comprehensive account of COS development, ultimately facilitating the formulation of guidance in this area. Gargon E, Gurung B, Medley N, Altman DG, Blazeby JM, Clarke M, Williamson PR: **Choosing important health outcomes for comparative effectiveness research: a systematic review**. PLoS ONE 2014,**9**:e99111.

PRM239
CAN ACTIGRAPHY OUTCOME MEASURES FROM EXISTING CLINICAL TRIALS PROVIDE A FRAMEWORK FOR SLEEP AND ACTIVITY ENDPOINT STANDARDS IN THE CLINICAL TRIAL OF THE FUTURE?

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OBJECTIVES: The growing market for personal wellness technology has increased the awareness of the potential role of sleep and activity measures in clinical trials. However there is significant debate around the clinical value of these endpoints, position of the devices and duration of the recording period. 90 Industry Sponsored Trials were identified from a comprehensive review of Clinical Trials.gov, EU Clinical Trials Register and The International Standard Randomised Controlled Trial Number register (ISRCTN) as having used Actigraphy (activity and sleep) derived outcome measures. This retrospective analysis is designed to establish if there is commonality among the existing Actigraphy endpoints and study design that can provide a framework for future clinical trials. **METHODS:** Systematic review of the subset of industry sponsored trials which had been filtered using the word "Actigraphy" and the brand names of the best known devices. These trials were then subdivided by therapeutic areas and analysed for outcome measures and study design. **RESULTS:** Therapeutic Areas (CNS, Dermatology, Respiratory, Cardiovascular, Diabetes, Oncology), Discrete and Common Endpoints: Sleep (47%), Activity (23%), PLM (12%). Wear time: when stated varied from 10 hours to 4 weeks. **CONCLUSIONS:** The preponderance of the trials reviewed were in the CNS therapeutic area (73%). Actigraphy derived endpoints were used both as primary and secondary outcome measures. Sleep endpoints were the most common outcome measures, however there was considerable variability regarding the sleep parameter selected, the terminology used in the protocols and the wear time. In order for the value of Actigraphy derived endpoints to be maximised and universally adopted, the choice of endpoint and study design need to be standardized.

PRM240
USE OF SIMULATION TO ASSESS THE IMPACT OF A REMOTE MONITORING SYSTEM

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